

Exhibit 31

Corporate Compliance Quarterly Report to Board of Directors 2Q2011

July 21, 2011

**Bert Weinstein
Vice President, Corporate Compliance**



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Summary

- Corporate Integrity Agreement (CIA) – One year left to go
- Overview of R&D and Sales Compliance Priorities
- Sunshine Act and Aggregate Spend
- Speaker Programs, Retention of Healthcare Professionals
- Hotline Calls and Other Inquiries
- Monitoring of Purdue's Sales Force



Corporate Integrity Agreement

- Purdue's Corporate Integrity Agreement has one year remaining as of July 31st
- All requirements under the CIA have been met in Reporting Period 4, including all critical field-based CIA requirements such as the required number of Field Contact Reports (FCRs), with well over two times the required five day minimum of ride-alongs monitored through June.
- There have been no Reportable Events to report to the Office of Inspector General during this quarter.



CIA- Sales Promotion Monitoring – 2Q11

Purdue's CIA requires Corporate Compliance review of Field Contact Reports (FCRs) with a compliance category rating of "1," indicating less than 100% compliance with Sales SOPs

- 873 FCRs were prepared during 2Q11
 - 82 FCRs had a Compliance Rating of "1"
 - 10 required more complete Compliance review
 - 2 investigations resulted in the representatives receiving coaching letters
 - 8 are currently still under investigation pending additional follow-up centering on inaccurate or inappropriate product claims



CIA Medical Services Monitoring – 2Q11

Purdue's CIA requires review of certain HCP inquiries to Purdue's Medical Services Department regarding sales representative referrals (reflects OIG's general concern for off-label or improper promotion)

- During 2Q11 there were a total of 7858 Inquiries received by Medical Services concerning *all products*
 - 2486 of these inquiries pertained to OxyContin and Ryzolt, the "Covered Products" during CIA year 4
 - 46 of these inquiries fell into CIA specified categories/topics, and 38 of these inquiries required review, with no improper matters noted



Compliance Risk Assessment

- As with any risk-management activity, risk identification and prioritization is an important and continuing exercise to limit compliance exposures.
- At Purdue, Corporate Compliance builds business unit accountability for compliance through senior executive participation in compliance committee action.
- Compliance committee activity focuses on analysis of risk, based on the enforcement environment and the company's business activities, and seeks to limit exposure through a variety of actions, including policies, SOPs, training, and auditing and monitoring
- The following slides highlight this process for Sales and Marketing and R&D this year



Sales and Marketing

"Risk Area"

- Proper promotion
- CIA and Sales SOP Standards
- Material Review and use
- Fee for service arrangements
- Speaker programs
- Direct to consumer advertising
- E-marketing
- Sales force training
- Pricing
- Coupons / Value Cards
- Suspect prescribers

Activity

- Policies, training, monitoring
- Focused actions, monitoring
- New electronic system
- Meeting OIG Safe Harbor fully
- Training, monitoring
- Material review, monitoring
- Material review, monitoring
- Audit, monitoring
- Law & Finance oversight, audits
- Call note review, auditing
- "ADD" program, Law oversight



R&D

"Risk Area"

- Data Integrity
- CRO oversight
- Fee for service arrangements
- Conduct of clinical trials
- Subject protection / consents
- DSP Reporting
- Scientific publications
- Clinical Trials registration and reporting

Activity

- CRO oversight, auditing, monitoring
- Quality Assurance (QA) and Compliance
- Compliance oversight, monitoring
- Clin. Ops, Med. Res, Compliance oversight
- QA, Clin. Ops., Compliance oversight
- DSP oversight, monitoring
- Sci. Comms. Dept., Compliance oversight
- Sci. Comms. Dept., Compliance oversight



Federal Physician Payments Sunshine Act

As you are aware, 2010 Federal healthcare reform legislation requires pharmaceutical, biologic, and medical device manufacturers to annually report to the Department of Health and Human Services, and post on public website, payments and other transfers of value furnished to **Physicians** and **Teaching Hospitals**, including meals, gifts, consulting fees, etc.

- **April 1, 2012** – Sample reporting for 2011 due
- **January 1, 2012** –must start tracking transfers of value
- **March 31, 2013** – Report due for calendar year 2012



State Law Reminder!

Vermont - “No Gifts” law (no meals or gifts)

- Applies to all VT licensed HCPs wherever situated

Minnesota - \$50 total annual meal/gift limit to HCPs from all Purdue sources; Purdue spend is reserved for sales reps

Massachusetts - all meals by any employees, including those hosted by home office personnel, to be in the HCP’s office or in-hospital and accompanied by an informational presentation

Exception – If basis of interaction is a *bona fide* personal and reciprocal relationship



Speaker Program/Physician Retention

- Speaker programs are a high risk activity, in view of the potential for off-label or other improper promotional conduct by third parties during such activities
- A manageable risk with appropriate safeguards in place
- Corporate Compliance has worked closely with Sales and Marketing and others to implement appropriate controls for Butrans speaker programs.
- Live monitoring - independent monitors attend a significant sample of such programs nation-wide to evaluate and report to us on programs.
- All programs monitored by a Purdue attendee
- Expert consultant on Fair Market Value compensation of speakers and other Healthcare Professionals has completed analysis of Purdue's HCPs and published FMV criteria to be applied company-wide to all such arrangements.
- OIG requirements and recommendations closely followed



Hotline Calls and Other Inquiries 2Q2011



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Hotline and Other Inquiries 2Q2011

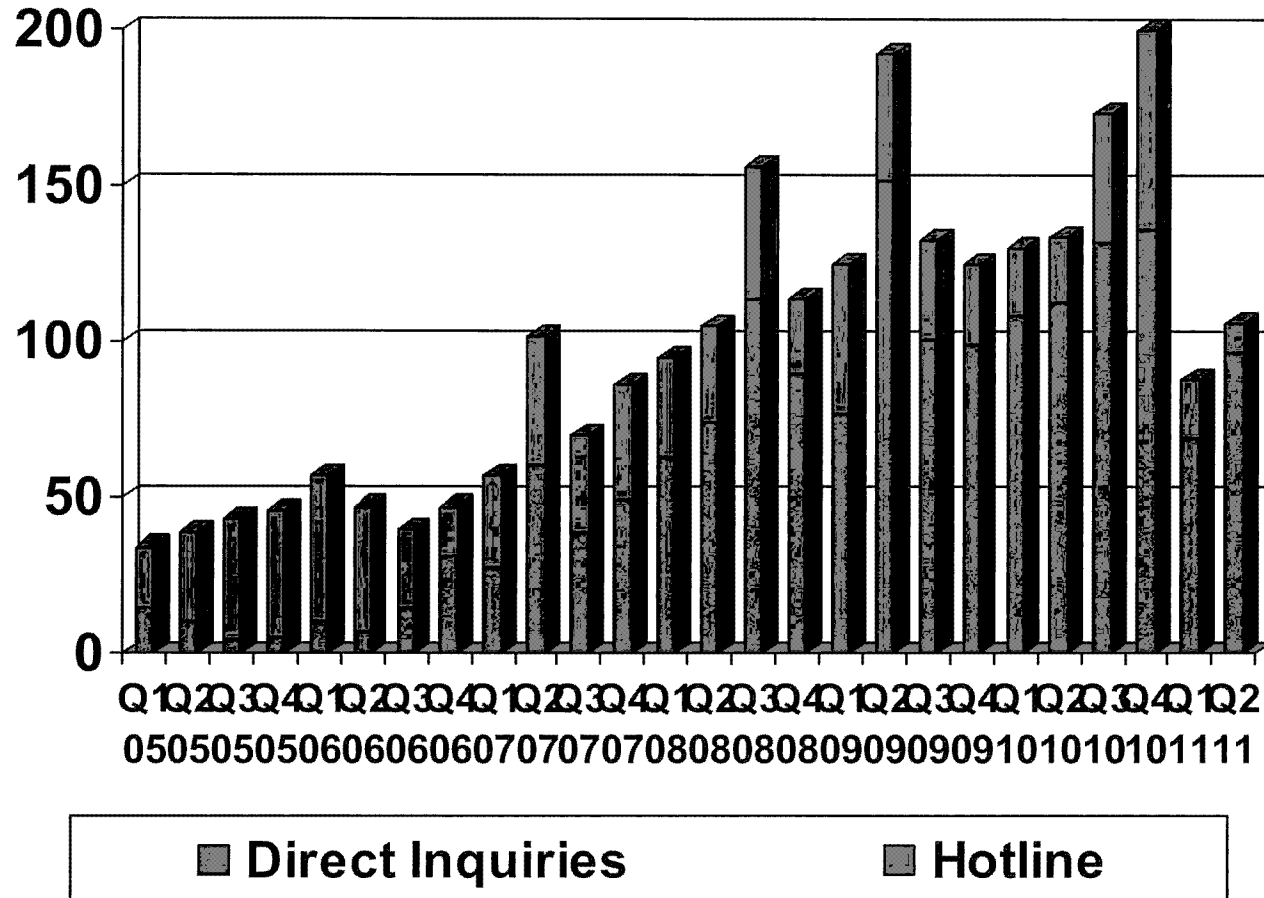
Compliance had 106 matters closed in 2Q2011, including:

- 73 Sales and Marketing matters relating to promotion, marketing materials, gifts, meals, CIA compliance, and grants (no longer including numerous institutional policy reviews in these data)
- There are a small number of open sales investigations into representative call notes concerning potential improper promotion and violations of Sales Department SOPs. All open matters are reviewed at our monthly Reportable Events Committee meetings, and none of these was deemed to rise to the level of CIA Reportable Events.

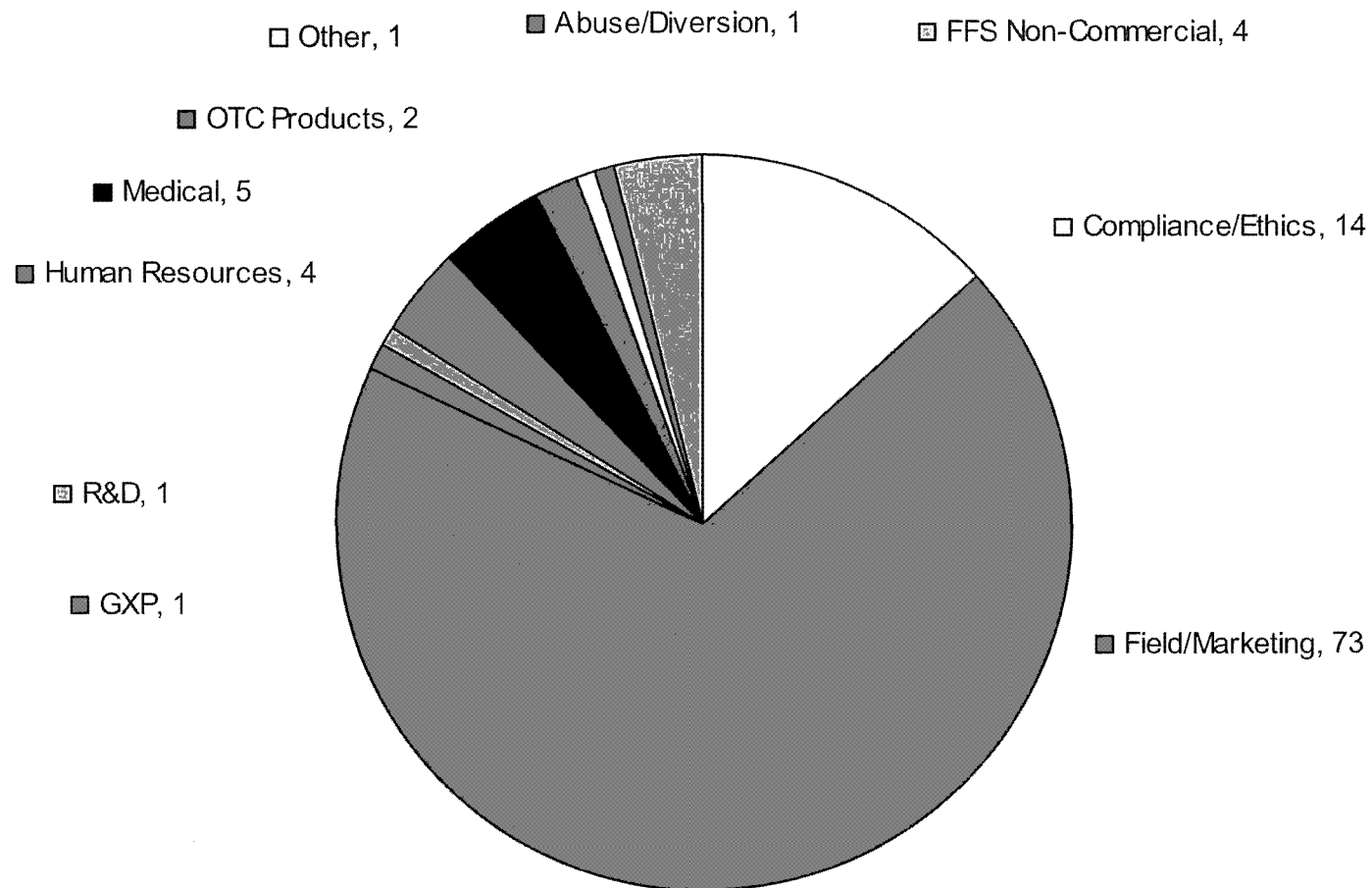
(The significantly fewer 2Q matters is attributed to reduction in OxyContin inquiries and elimination of institutional policy reviews from this database)



Inquiries by Quarter (1Q05 – 2Q11)



2Q 2011 Compliance Inquiries



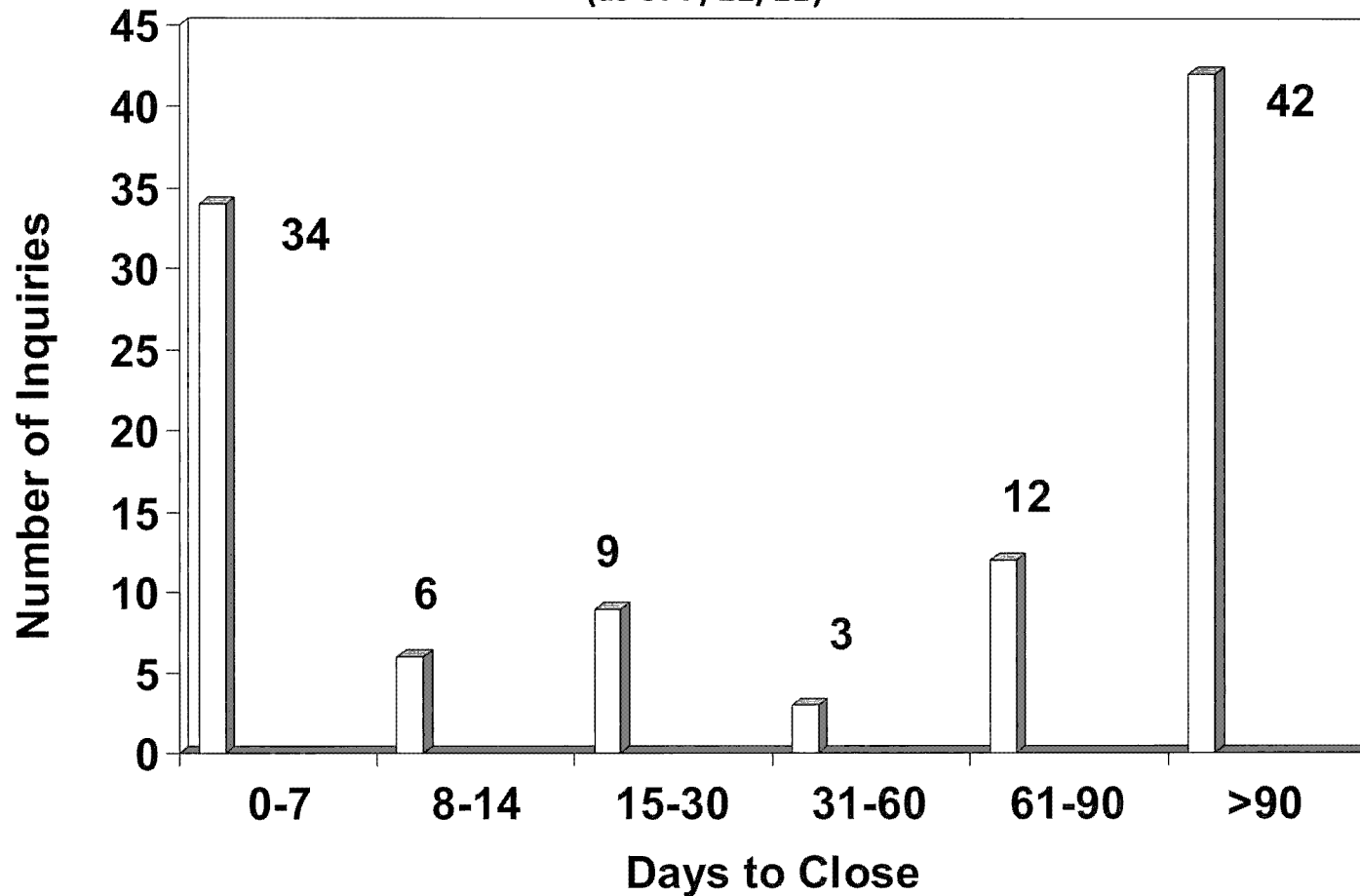
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Inquiry Response Time

Days to Close Inquiries 2Q 2011
(as of 7/11/11)



How is Purdue's Sales Force Monitored?



Sales Force Monitoring

- Sales Management Activities
 - District Manager (DM) Call Note Reviews and “Call Note Annotations”
 - DM Ride-Alongs: 8-12+ full days/year
 - Field Contact Reports: detailed documentation and discussion of representative’s promotion activity
 - Reviewed by Regional Directors and Management
- Non-DM Ride-Alongs
 - Corporate Compliance
 - Sales Managers, District and Regional Field Trainers
 - Law
 - Sales Training
 - Others



Sales Force Monitoring

- Field Contact Reports reviewed by Corporate Compliance
 - Representative compliance performance rated against 12 compliance categories – any not rated fully compliant results in detailed review

- Monthly Call Note Review Process – analyzes all call notes for 30 key words, such as: dosing, formula, benefit, abuse, safer, milder
 - 125,000+ call notes generated by field each month
 - ~25% of call notes have “hits” on key words
 - All notes with hits reviewed
 - Final Analysis by Corporate Compliance – approximately 100 per month



Sales Force Monitoring

■ *PLUS:*

- Adverse Event Reporting
- Medical Information Requests
- Product Complaints
- Abuse, Diversion Detection Reporting
- Expense Reporting
- Speaker Program monitoring
- Live Training / Sales meetings
- Hotline matters
- Direct contacts to Compliance



Sales Force Monitoring

- Weekly Meetings of Sales Discipline Committee
 - Centralizes, tracks and collaborates on “sales” investigations matters from inception to conclusion
 - Standing members include: Human Resources, Law, Corporate Compliance, Sales
 - Decides scope, nature and participants for investigations, addresses individual and organizational remediation activities, and discipline
 - All matters officially archived and retained
- Monthly Reportable Events Committee meetings decide on reporting to Office of Inspector General under CIA
- Quarterly Compliance Council meetings review major matters, audits, monitoring activities
- Sales and Marketing Compliance Committee, meets every six weeks, addresses key compliance risks and issues



How Does the Sales Monitoring “System” Work in Practice?

An Example...



Emails to Customers

- A newer sales representative was speaking with a more tenured representative and indicated that she had sent emails to some of her customers.
- Tenured representative reminded new representative that this is a violation of Sales SOP:

Correspondence with HCPs

Sales Representatives generally are not permitted to draft and/or send correspondence to any Health Care Professional (HCP) that has not previously gone through the internal Material Review Process and received written approval for distribution, except as provided below.

Individualized email communications may be drafted and sent solely for purposes of arranging and/or confirming an office visit. In such cases, the Representative is required to copy his/her District Manager on such correspondence and must avoid any mention of product, product attributes, competitor products, disease states, and/or specific patients. Model language for such emails is provided in the "Email Communications by Representatives" document on the Phoenix homepage in the Desktop Library.

- New representative self-reported the violation to her Manager.
- Manager alerted home office, which kicked off an investigation.



Investigation

- Home office initiated an investigation and began by looking at emails sent by field sales personnel to external recipients that included references to Butrans.
 - Revealed more than 40 employees who had sent or received emails to customers that included references to Butrans. Few of these were major issues.

MINOR

MAJOR



Customer reference to Butrans

Rep email including claims

- Law and Compliance reviewed all email and categorized each based on content:
 - Discussion of Butrans, including claims
 - Discussion of “new” or “unique” pain medication
 - Discussion of pain medication
 - Product reference by customer with no response from representative
 - Other
- Conducted investigations with representatives who had more significant violations.



Outcomes

- **Discipline**
 - Major Discipline for one representative – probation and removal from a training leadership position in the field.
 - 13 representatives received written warning letters.
 - 30 representatives received coaching emails.
- **Retraining**
 - A bulletin was sent to all field force personnel reminding them of the current policy.
- **Edits to the Emails to Customers Policy and Development of New Tools to Promote Compliance**
 - Sales Management and Compliance agreed to revise the policy to allow more flexibility in contacting a customer.
 - Compliance and IT currently collaborating to develop a tool through Phoenix that will allow customized email to a customer that includes approved product-specific language.



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